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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,862	02/27/2002	Steffen Schlehuber	029029-0101	3214

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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,862

Applicant(s)

SCHLEHUBER, STEFFEN

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of claims

Claims 1-17 are pending

Preliminary amendment filed 26 September 2002, which amends claims 3, 5-8, 13, 15 and 17, and applicants' request (filed 6 May 2002) for extension of time of one month have been entered. The following Office action is applicable to the pending claims 1-17.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-7, drawn to a bilin-binding (mucin) polypeptide.

Group II, claims 8-15, drawn to a polynucleotide encoding the polypeptide of Group I, and a method of producing digoxigenin-binding mucin of the bilin-binding polypeptide and a method of making a fusion protein comprising said digoxigenin-binding mucin; both of said methods are directed to use of said polynucleotide for making the polypeptide and the fusion protein thereof.

Group III, claims 16-17, drawn to a method of using the polypeptide of Group I to bind digoxigenin or a digoxigenin conjugate with proteins, and a method of detecting the digoxigenin group in a mucin of the bilin-binding protein, or fusion protein that contains the mucin thereof, comprising subject said mucin, or said fusion protein, to random mutagenesis and selecting and isolating the resulting mucin which has desired binding affinity for the digoxigenin group.

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Group IV, claims 16-17, drawn to a method of using the polypeptide of Group I to bind digoxigenin or a digoxigenin conjugate with nucleic acids, and a method of detecting the digoxigenin group in a mutein of the bilin-binding protein, or fusion protein that contains the mutein thereof, comprising subject said mutein, or said fusion protein, to random mutagenesis and selecting and isolating the resulting mutein which has desired binding affinity for the digoxigenin group.

Group V, claims 16-17, drawn to a method of using the polypeptide of Group I to immobilize or remove digoxigenin or a digoxigenin conjugate with proteins, and a method of detecting the digoxigenin group in a mutein of the bilin-binding protein, or fusion protein that contains the mutein thereof, comprising subject said mutein, or said fusion protein, to random mutagenesis and selecting and isolating the resulting mutein which has desired binding affinity for the digoxigenin group.

Group V, claims 16-17, drawn to a method of using the polypeptide of Group I to immobilize or remove a digoxigenin conjugate with nucleic acids, and a method of detecting the digoxigenin group in a mutein of the bilin-binding protein, or fusion protein that contains the mutein thereof, comprising subject said mutein, or said fusion protein, to random mutagenesis and selecting and isolating the resulting mutein which has desired binding affinity for the digoxigenin group.

Group VI, claims 16-17, drawn to a method of using the polypeptide of Group I to detect or determine digoxigenin or a digoxigenin conjugate with proteins, and a method of detecting the digoxigenin group in a mutein of the bilin-binding protein, or fusion protein that contains the mutein thereof, comprising subject said mutein, or said fusion protein, to random mutagenesis and selecting and isolating the resulting mutein which has desired binding affinity for the digoxigenin group.

Group V, claims 16-17, drawn to a method of using the polypeptide of Group I to detect or determine a digoxigenin conjugate with nucleic acids, and a method of detecting the digoxigenin group in a mutein of the bilin-binding protein, or fusion protein that contains the mutein thereof, comprising subject said mutein, or said fusion protein, to random mutagenesis and selecting and isolating the resulting mutein which has desired binding affinity for the digoxigenin group.

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The invention listed as Groups I -V do not related to a single general invention concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason: Group I and Group II are patentably distinct from one another because of the materially different structures of the compounds claimed. The Group I is drawn to polypeptide while Group II to a polynucleotide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use. Thus, the products of these two Groups are deemed not to constitute the same technical feature.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Applicants are advised that reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Samuel Wei Liu, Ph.D.

May 19, 2004



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER